Applicant: Kosuke Seiki et al. Attorney's Docket No.: 11283-014001 / PH-787PCT-

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# **REMARKS**

## Claim Objections

Claim 1 has been amended to fully recite the abbreviated L-PGDS. Withdrawal of this objection is requested.

## Claim Rejections - 35 USC §112

Claims 1 to 7 have been rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

Claim 1 has been amended to incorporate additional steps to indicate that whether restenosis develops or not is based on the concentration changes in L-PGDS within the first 48 hours after the coronary intervention. Claims 2 and 3 have been amended to indicate how many times the L-PGDS concentration is measured before and after the coronary intervention. Claims 1, 2, and 3 have been amended to obviate the indefinite rejections.

#### Claim Rejections - 35 USC §102

Claims 1 to 7 have been rejected as being anticipated by Eguchi et al. Claims 1 to 7 have been rejected as being anticipated by Oda et al. Applicants respectfully submit that claims 1 to 7 are not anticipated by Eguchi et al. or Oda et al. for the following reasons.

#### Claim 1 recites as follows:

1. (Currently Amended) A method for predicting restenosis following coronary intervention comprising:

measuring a lipocalin-type prostaglandin D synthase (L-PGDS) concentration in a body fluid sample extracted from a subject at least twice between immediately before the coronary intervention and 48 hours after the intervention; and

predicting whether restenosis develops or not based on whether the L-PGDS concentration substantially increases or not within 48 hours after the intervention.

Eguchi et al. discloses acute occlusion by thrombosis which generally happens several hours after PTCA and hardly occurs after 7 days following PTCA (see page 14693, right

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column). Restenosis, on the other hand, generally occurs 3 to 4 months after PTCA. Thrombotic occlusion and restenosis are two completely different complications and this distinction is explained on page 2, lines 10 to 13 of the present specification. Therefore, Eguchi et al. does not present any method for predicting the occurrence of restenosis. Furthermore, Eguchi et al. does not disclose measuring the L-PGDS concentration between immediately before the coronary intervention and 48 hours after the coronary intervention to predict whether restenosis will or will not occur. Thus, claim 1 and its dependent claims 2 to 7 are not anticipated by Eguchi et al.

Oda et al. describes a method of measuring the L-PGDS concentration before and after PTCA in Example 4, Fig. 7. However, Oda et al. only describe that the L-PGDS concentration in a subject with angina pectoris is higher than that of a normal subject, and that the concentration in a subject with angina pectoris decreases to a normal level after PTCA. Based on this result, Oda et al. suggests that the higher concentration of L-PGDS indicates a greater risk of suffering from angina pectoris. Oda et al. does not disclose measuring the L-PGDS concentration between immediately before the coronary intervention and 48 hours after the coronary intervention to predict whether restenosis will or will not occur, as claimed in claim 1. Therefore, claim 1 and its dependent claims 2 to 7 are not anticipated by Oda et al.

# New Claims

Claims 8 to 19 have been added. Claim 8 and 12 are supported, for example, on page 5, line 6 from the bottom to page 6, line 10 from the top. Claim 9 is supported by claim 1 and the same passage in the specification as above. Claims 10 and 11 correspond to claims 2 and 3, respectively. Claims 2, 3, 10, 11, and 13 to 19 are supported by, for example, on page 11, lines 4 to 21. No new matter has been added.

# Claim Rejections - 35 USC §103

Claims 1 to 7 have been rejected as being unpatentable over Eguchi et al. As stated previously, restenosis by definition (see page 2 lines 10 to 13 of the present specification) is not the same as acute thrombosis described in Eguchi et al. The acute thrombosis occurs within several hours after PTCA. However, restenosis develops about 3 to 4 months after PTCA.

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Eguchi et al. is completely silent as to restenosis. Therefore, claims 1 to 7 would not have been obvious to a person of ordinary skill in the art from the teaching of Eguchi et al.

# Summary

For the foregoing reasons, pending claims 1 to 18 are believed to be allowable over the cited prior art references. Withdrawal of all the rejections is respectfully requested.